340B Program Puts Manufacturers At Risk of Duplicate Drug Discounts

To the Editor:

With all the recent news pertaining to the Public Health Service 340B Drug Discount Program (notably, the article written by Stephen Barlas, "Congress Likely to Reign in 340B Drug Discount Program," published in the October 2015 issue of *P&T*), I believe it is imperative also to focus attention on the risk of duplicate discounts to drug manufacturers. To be clear, a duplicate discount occurs when inventory subject to a 340B discount is also submitted for a Medicaid rebate, causing the drug manufacturer to pay two discounts on the same drug.

Since 2012, the Office of Pharmacy Affairs (OPA) has audited more than 350 covered entities for 340B program compliance. Among the covered entities audited, at least 25% of 340B programs had duplicate discount errors.[1] These findings demonstrate that duplicate discounts may occur in a significant portion of 340B drug purchases, creating a material financial risk to manufacturers.

Duplicate discounts are the direct result of a conflict between two federal programs: Medicaid rebates intended to benefit state Medicaid programs and 340B discounts intended to benefit eligible safety-net health care providers (340B-covered entities). Together, these programs have a substantial overlap in prescription eligibility, making it possible for both states and covered entities to claim a discount for the same purchase.

Three key pieces of legislation define the relationship between 340B discounts and Medicaid rebates:[1]

- The Omnibus Budget Reconciliation Act of 1990 created a discount price structure that allowed states to claim rebates for "traditional" fee-for-service Medicaid drugs.
- The Veterans Health Care Act of 1992 created a discount pricing structure that allowed covered entities to purchase drugs at a reduced price (the 340B discount). It also recognized a financial risk to manufacturers and legislated that manufacturers will not be required to pay both a 340B discount and a Medicaid rebate.
- The Patient Protection and Affordable Care Act of 2010 expanded state Medicaid rebates to include drugs dispensed under MCO plans.

In theory, 340B-covered entities are expected to track and manage 340B inventory and to ensure that it is excluded from Medicaid rebate requests.[2] The original control for this is referred to as the Medicaid Exclusion File. The extension of Medicaid rebates to managed care organizations (MCOs) exacerbates the duplicate-discount problem. Compelling states to claim Medicaid rebates for drugs dispensed through MCOs (instead of only fee for service) significantly increases the total number of Medicaid rebate claims and the potential for overlap with 340B. This growth in the volume of rebate claims increases the likelihood that state Medicaid agencies will request rebates for drugs already purchased at a 340B discount. While the 340B statute clearly assigns responsibility for preventing fee-for-service Medicaid duplicate discounts to covered entities, the Centers for Medicare and Medicaid Services and the Health Resources and Services Administration place responsibility for Managed Medicaid duplicate-discount prevention on the plans themselves for MCO claims.

Finally, the proliferation of third parties "participating" in 340B has increased the complexity of program management. Most covered entities now have extensive contract pharmacy networks and outsource their 340B program implementation and operation to third-party administrators, thereby limiting the covered entities' visibility into their program utilization. These administrators do not share a common understanding of 340B claim qualification and inventory management. Many do not adjust for, or even recognize, Medicaid claims that should be carved out of 340B inventory purchases.

The prevention of duplicate discounts requires an automated process to monitor and differentiate continuously the status of prescription claims. But as mentioned previously, the processing of 340B and Medicaid prescriptions splits at the point of sale; the data sets become independent and managed by separate parties for different purposes. Pharmacies have one view to manage their inventory; covered entities, along with their administrators, have another view to manage 340B program financials; and state Medicaid agencies have yet another view generated by point-of-sale adjudication. Each data set is incomplete, and no single party can see the whole picture. There is currently no mechanism to bring the necessary data back together for purposes of preventing duplicate discounts.

In my opinion, regulatory oversight of the 340B program is insufficient given its complexity. The OPA's lack of regulatory authority has allowed program controls to become inadequate to protect manufacturers from paying duplicate discounts. Guidelines have not kept pace with the rapid increase in program participation, and there is no clear mechanism in place to ensure program integrity with respect to its overlap with Medicaid.

While covered entities and, to some extent, MCOs have been identified as responsible for preventing duplicate discounts, they have failed to do so adequately. By default, this responsibility falls to manufacturers. To effectively detect duplicate discounts, manufacturers must review detailed data for drugs purchased at 340B prices and compare this information with state Medicaid rebate claims data. Current controls make these data difficult to acquire, but reconciliation of these two data sources is necessary to mitigate the potential financial exposure.

My advice to manufacturers is simple: Understand your company's 340B duplicate discount risk and take steps to minimize it because the current program implementations fail to do so. Fortunately, program guidelines have repeatedly affirmed manufacturers' authority to review 340B program implementation, to dispute Medicaid rebate claims suspected of being erroneous, and to seek remediation if duplicate discount errors are discovered. Manufacturers must exercise this authority if they are to take control of their duplicate discount risk.

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